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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,826	02/08/2002	Mitchell F. Brin	17326CIP2 (BOT)	2841

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,826	BRIN ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6,8-15,18-20,32 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 6, 8-15, 18-20, 32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/10/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments and Amendments

Election/Restrictions

1. The Examiner apologizes for overlooking Applicants' election with traverse of Group I in the reply filed on July 14, 2005. The traversal was on the ground(s) that all of the claims were limited to the use of Clostridial neurotoxin and a single search would suffice to search all the claims, see page 3 of Remarks submitted July 14, 2005. This was not found persuasive because all the claims were not limited to just botulinum toxins opposed to the genus of Clostridial neurotoxins, which mandated an extensive search.

The requirement is still deemed proper and is therefore made FINAL. Additionally, the Examiner did call Mr. Donovan at his office on June 16, 2005 at 9:15 am EST leaving a voice mail noting any questions regarding the message could be addressed by calling the Examiner and in the meantime a Requirement would be sent.

2. Claims 1, 4, 6, 8-15, 18-20, 32 and 33 are pending.

Claims 2, 3, 5, 7, 16 and 17 have been cancelled.

Claims 1, 4, 6, 10-12, 14, 15, 20, 32 and 33 have been amended.

Claims 1, 4, 6, 8-15, 18-20, 32 and 33 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

4. The information disclosure statement (IDS) filed April 10, 2002 has been continues not be considered in its entirety. The Examiner appreciates Applicants' resubmission of Reference CD and the information referred to therein has been considered.

Specification

5. The disclosure is no longer objected and moot because Applicants note there are no drawings in the instant application, see Remarks submitted November 23, 2005, page 5.

Withdrawn Rejections

Claim Rejections - 35 USC § 102

6. The rejection of claims 1, 6-8, 10-14 and 33 under 35 U.S.C. 102(b) as being anticipated by Schwartz et al. is withdrawn in light of Applicant's arguments and claim amendments. Claims 2 and 5 have been cancelled.

Claim Rejections - 35 USC § 103

7. The rejection of claims 1, 6-8, 10-14 and 33 under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (Movement Disorders 13(1): 188-190, January 1998/ IDS reference CB submitted June 16, 2003), in view of U.S. Patent number 6,143,037

(filed June 12, 1996) is withdrawn in light of Applicants' arguments and claim amendments. Claims 2 and 5 have been cancelled.

8. The rejection of claims 1, 8 and 33 under 35 U.S.C. 103(a) as being unpatentable over WO 94/24155 (27 October 1994) is withdrawn in light of Applicants' arguments and amendment to claims 1 and 33.

Double Patenting

9. The provisional rejection of claims 1-4, 7-15, 18-20, 32 and 33 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/929,040 (filed 08/27/2004) is withdrawn in light of the terminal disclaimer filed and submitted November 23, 2005 and its subsequent approval.

Maintained Rejection

Claim Rejections - 35 USC § 112

10. The rejection of claims 1, 4, 7-15, 19, 20, 32 and 33 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating a mammary gland disorder with *Clostridial neurotoxin botulinum* toxin A and *Clostridial difficile* toxin A, does not reasonably provide enablement for treating a mammary gland disorder with any Clostridial neurotoxin or preventing development of a mammary gland neoplasm/carcinoma is maintained. Claims 2, 3, 5, 16 and 17 have been cancelled.

Applicant asserts, "The botulinum toxins comprise a family of pharmacologically similar toxins that block acetylcholine release from peripheral nerves and cause a flaccid paralysis. All of the stereotypes of toxin can poison humans and other animals..." (page 81, left hand side of Schantz, E.J., et al), see Remarks, submitted November 23, 2005, page 6, section V. Applicant concludes arguments noting "...all of the botulinum toxins act through the same physiological mechanism...[and] not just botulinum toxin type A, is enable by the specification.", see Remarks, page 6, last paragraph.

The Schantz article, as well as Applicants' arguments and points of view have been considered, but found unpersuasive. Applicants' "sweeping statement" regarding botulinum toxins comprise a family of pharmacologically similar toxins does not preclude the instant rejection. Schantz does not provide sufficient evidence substantiating Applicants' position that all botulinum types, A-F and G would effectively treat a broadly termed mammary gland disorder. The analysis provided in the first action on the merits (FAOM) mailed Ocotober 14, 2005 establishes the unpredictability of treating cancer and the differences between the toxin types, see Hatheway (provided with the FAOM), page 69, Table 2 and page 77, Table 4. The treatment of specific mammary diseases with C. botulinum type A and C. difficile toxin A neurotoxins cannot be extrapolated to the treatment of all mammary diseases with all the toxin types. Thus, one of skill in the art could not practice the broadly claimed method, of treating all mammary gland disorder with all botulinum toxin types with a reasonable expectation of success.

Claim Rejections - 35 USC § 103

11. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (Movement Disorders 13(1): 188-190, January 1998/ IDS reference CB submitted June 16, 2003).

In anticipation of a rejection Applicants argue the latissimus dorsi muscle is not a part of the mammary gland and botulinum toxin treatment of this muscle is not anticipatory of the claims, see Remarks, page 7, section VI. Applicant's arguments and points of view have been carefully considered, but found unpersuasive.

Schwartz teaches a method of treating neuromyotonia in a muscle flap of the left breast with an injection of 300 U botulinum A toxin into a latissimus dorsi flap, see title and page 188, paragraph before "Discussion" section. The location of this injection is within the vicinity of the precancerous breast tissue as stated in claim 12. This disorder is considered precancerous given there was no disclosure of any cancer associated with the disorder. This mammary gland disorder was characterized by the left breast expanding and elevating during a 24 hour period, see page 188, Case Report section, second paragraph. Intrinsically, the treatment of the said disorder with the botulinum toxin A would cause about 20% - 100% reduction in the diameter of the mammary gland tissue with the subsequent reported reduction in the activity of the said tissue, see page 188, last paragraph before Discussion section. Schwartz does not teach the claimed method wherein the administration of the botulinum toxin is between about 10^{-2} U/kg and about 200U/kg.

However, although the claims recite these specific dosages of the botulinum

toxin, no positive recitation of the methods distinguishes the claims over the reference. Therefore, the reference reads on the treatment with the specified amount of botulinum toxin. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to determine and administer an effective range of toxin in order to further limit comprising the individual's health. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success since dosages of any composition for treatment must be adjusted and optimized. Thus the claimed subject matter is considered obvious over the prior art, absent sufficient factual evidence to the contrary.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
10 March 2006